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SEP 2 9 2000

510(k) Summary

Bravo pH Monitoring System™

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR §876.1400 for the Bravo pH Monitoring System™.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

William A. Knape
Clinical Pathways
17485 Monterey Road, Suite #14
Morgan Hill, CA 95037
Telephone: (408) 776-7001
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Contact Person: same

Date Prepared: June 30, 2000

Name of Device and Name/Address of Sponsor

Bravo pH Monitoring System™
Endonetics, Inc.
5830 Oberlin Drive, Suite #102
San Diego, CA 92121

Common or Usual Name

Gastric Reflux pH Measurement/Monitoring System

Classification Name

Stomach pH electrode

Predicate Devices

The Bravo pH Monitoring System™ has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. The Bravo pH Monitoring System™ is substantially equivalent in materials, design and intended use, to the following predicate devices; Medtronic Functional Diagnostics' Zinetics 24™ Single-Use pH Catheter Sandhill Scientific's ComforTEC Single-Use Internal Reference pH

Probe, Medtronic Functional Diagnostics/ Synectics' Digitrapper Mk III, Sandhill Scientific's BioSTAR pH Monitoring System, and Medtronic Functional Diagnostics Synectics' EsopHogram Reflux Analysis Module of Polygram for Windows.

Intended Use

The Bravo pH Monitoring System™ with Accessories is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux. The pH probe can be delivered and placed endoscopically or with standard manometric procedures. The pH Software Analysis Program is intended to record, store, view and analyze gastroesophageal pH data to diagnose reflux disorders.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Endonetics Bravo pH Monitoring System™ and the predicate devices are substantially equivalent and have the same intended use.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2000

Endonetics, Inc.
c/o William Knape
Clinical Pathways
17485 Monterey Road, Suite 200
Morgan Hill, CA 95037

Re: K002028
Bravo™ pH Monitoring System and Accessories
Dated: June 30, 2000
Received: July 3, 2000
Regulatory Class: I
21 CFR §876.1400/Procode: 78 FFT

Dear Mr. Knape:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

510(k) Number (if known): K002028

Device Name: Bravo pH Monitoring System™ and Accessories

Indications For Use: Bravo pH Monitoring System™ with Accessories is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux. The pH probe can be delivered and placed endoscopically or with standard manometric procedures. The pH Software Analysis Program is intended to record, store, view and analyze gastroesophageal pH data.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K00 2028